UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,807	02/20/2004	Tetsuo Shibuya	JP920030020US1	7767

7590 11/29/2006

William E. Lewis
Ryan, Mason & Lewis, LLP
90 Forest Avenue
Locust Valley, NY 11560

EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,807	SHIBUYA, TETSUO	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *4-7,10-12,15,16,18 and 19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,9,13,14 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2202004, 7272004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1-3, 8-9, 13-14, and 17), filed 9/14/06, are acknowledged. Claims 4-7, 10-12, 15-16, and 18-19 are withdrawn from consideration as being drawn to non-elected Groups.

Applicant's traversal is on the grounds that each Group is directed to systems for screening a predetermined nucleotide sequence to efficiently determine whether or not the sequence constitutes a portion of another nucleotide sequence. Applicant argues that differences such as use of a partial short chain sequence and use of a server would not add any undue search burden in examination.

The applicants' request to combine Groups I-III into one invention was found unpersuasive because of the following reasons (summarized from the restriction paper):

Inventions in Groups I-III contain methods/systems/programs/computer readable storage media that do recite structurally and functionally distinct elements, are not required for the other, and/or achieve different goals/steps. Group I involves evaluating target nucleotide sequence data without a network or server that is not required by any other group. Group II requires designating a partial short chain sequence and evaluating complementary sequence data on the basis of every partial sequence that is not required in any other group. Group III utilizes a server comprising a sending and receiving unit utilizing a network that is not used in any other group. These distinct methods/systems/programs are often separately characterized and published in literature and would add undue search burden if they were all examined together. Thus, they are considered distinct invention types for restriction purposes.

The requirements are still deemed proper and are therefore made FINAL.

The drawings, filed 2/20/04, are objected to by the Examiner due to the presence of sequence compliance issues with Figures 1a and 1b and Figures 11 and 12 (see below).

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, Figures 1a and 1b. It is noted that the specification has been amended, filed 7/12/04. However, only four of the five sequences listed in Figures 1a and 1b have been given SEQ ID Nos. In addition, the amended specification refers to Figure 11 as having sequences with SEQ ID Nos when it is really Figure 12 that has the sequences. Therefore, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because it lacks SEQ ID Nos cited along with each sequence in the Figures. Applicants are also reminded that SEQ ID Nos are not required in Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. It is noted that the Detailed Description of the Preferred Embodiments states the corresponding SEQ ID Nos, but not the Brief Description of the Drawings Section. Applicant(s) are required to submit a new computer readable form sequence listing, and a paper copy, or CD-ROM incorporated by reference into the specification, statements under 37 CFR § 1.821 (f) and (g), if there is a need to list additional sequences in the sequence listing. Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

The information disclosure statements, filed 2/20/04 and 7/27/04, have been considered by the Examiner.

Claims herein under examination are 1-3, 8-9, 13-14, and 17.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 8-9, 13-14, and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (published in the O.G. notice (1300 OG 142) on 11/22/2005) a method that does not result in a physical transformation of matter MAY be statutory where it recites a concrete, tangible and useful result; i.e. a practical application.

In the instant case, claims 1-3, 8-9, 13-14, and 17 are directed to a computer system, method, a program, and a computer readable storage medium for screening nucleotide sequences. It is noted that claims 13-14 and 17 are directed to non-statutory subject matter, because they are directed to a program or a computer-readable storage medium recording a program. Also, claims 1-3, 8-9, 13-14, and 17 do not result in a physical transformation of matter, nor is any concrete, tangible and useful result produced/recited. Therefore, these claims are not statutory.

LACK OF UTILITY

Claims 1-3, 8-9, 13-14, and 17 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 1-3, 8-9, 13-14, and 17 are directed to a computer system, method, program, and computer readable storage medium used for storing sequence data and evaluating data of nucleotide sequences.

It is not clear what one skilled in the art would use the computer system, method, program, and a computer readable storage medium for. It is not clear what is the "practical" result of the encoded software. The "usefulness" of a stored data and evaluated data is not apparent.

The instant invention involves storing a target nucleotide sequence and complementary sequence data and a generic evaluating result. Evaluating sequence data is potentially useful, but one of skill in the art would have to know something particular about the sequence or type of evaluation, such as tissue type, disease represented, or organism involved, in order for the utility to be specific. The specification on page 4 states that the invention provides a quick evaluation whether a probe will bind to a target sequence which may be used for generating testable hypotheses, that is not a specific utility because it is generally applicable to sequence homology in general. As stated above, the claims and specification fail to state what specific evaluation might be tested. The claims do not recite for WHAT the evaluation would be used. Instead, the claims merely recite storing an evaluation result, which IS generic. A utility does not need to be

recited in the claims; however, the utility must be of "immediate benefit" to the public (which means one must be able to use the CLAIMED invention for any asserted utility without further experimentation).

Further, the claimed invention is not supported by a substantial utility, because no substantial utility has been established for the claimed subject matter. Deciding to how to use the claimed stored evaluation result would require further research to confirm a "real world" context of use. Applicant mentions that on page 4 the invention provides a quick evaluation whether a probe will bind to a target sequence; however, this assertion would clearly require further research to confirm that such predicted binding were indeed possible. Further research would also be required to confirm the effective binding. Evaluating sequences without a specific and substantial utility does not define a "real world" context of use.

As set forth in Brenner v. Manson (148 USPQ 689 (1966)) and In re Ziegler (26 USPQ2d 1600), the "usefulness" of an invention must be immediately apparent to those familiar with the technological field of the invention. As further research would be required to "use" the evaluated result, the apparent result of the computer system, method, program, and computer readable storage medium is not "immediately useful" and lacks utility.

Due to a lack of either an art recognized or alleged well established utility, the instant invention has been rejected due to also lacking the required combination of a specific, substantial, and credible utility. Although it may be credible that the claimed invention has the above mentioned utilities, the lack of a specific and substantial utility, as explained above, sufficiently supports this rejection.

Claims 1-3, 8-9, 13-14, and 17 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 8-9, 13-14, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 1 (lines 5-6), 8 (line 6), 13 (line 6), and 17 (line 7) recite the limitation "the target nucleotide sequence" which lacks clear antecedent basis. While there is prior mention of target nucleotide sequence data, these data do not necessarily contain the sequence. Correction of this issue via clearer claim wording is requested. Claims 2-3, 9, and 14 are also rejected due to their dependency from claims 1, 8, and 13.

Claim 1 (line 7) recites "evaluating said target nucleotide sequence data and said complementary sequence data in descending order of edit distance" and claims 8, 13, and 17 recite "evaluating the binding possibility of said target nucleotide sequence data and said

complementary sequence data in descending order of edit distance" which are vague and indefinite. It is unclear what is being evaluated: target sequence data evaluated individually, target sequence data compared to other target data, target sequence data compared to complementary sequence data, complementary sequence data evaluated individually, or various other scenarios. It is unclear what Applicant intends "descending order of edit distance" to mean, particularly since the sequence data do not necessarily contain the sequences themselves. Clarification of these issues via clearer claim wording is requested. Claims 2-3, 9, and 14 are also rejected due to their dependency from claims 1, 8, and 13.

Claim 1 (penultimate line) recites the limitation "the evaluation result" and claims 8, 13, and 17 (last line) recite "the result" which lack clear antecedent basis as no such single result was previously mentioned. Clarification of this issue via clearer claim wording is requested. Claims 2-3, 9, and 14 are also rejected due to their dependency from claims 1, 8, and 13.

Claims 2, 8, 13, and 17 recite the limitation "maximum acceptable edit distance" and claims 3, 9, and 14 recite "maximum edit distance" which are vague and indefinite. It is unclear what Applicant intends these phrases to mean. Clarification of this issue via clearer claim wording is requested.

Claim 3 recites the limitation "dynamically determining termination of the evaluation" which is vague and indefinite. It is unclear what Applicant intends this phrase to mean. Clarification of this issue via clearer claim wording is requested.

Claim 8 recites the limitation "said each nucleotide sequence data" and claims 13 and 17 recite the limitation "said nucleotide sequence data" which lacks proper antecedent basis. It is unclear if these phrases are referring to the target sequence, the probe sequence, or both.

Clarification of this issue via clearer claim wording is requested. Claims 9 and 14 are also rejected due its dependency from claims 8 and 13.

Claims 8, 13, and 17 recite the limitation "said maximum edit distance" which lacks proper antecedent basis. While there is prior mention of "maximum acceptable edit distance", there is no previous mention of "maximum edit distance" which is not necessarily acceptable. Correction of this issue via clearer claim wording is requested. Claims 9 and 14 are also rejected due their dependency from claims 8 and 13.

Claims 8 and 17 recite the limitation "from each storing unit" which is vague and indefinite. As there is no previous mention of any unit, it is unclear if Applicant is referring to the storing step on line 4 or line 8 or both. Clarification of this issue via clearer claim wording is requested. Claim 9 is also rejected due its dependency from claim 8.

Claims 9 and 14 recite the phrase "said evaluation step" which is confusing. It unclear if this step is referring to the "step of reading out" of claims 8 and 13 which appears to include some evaluating, or if the "evaluating the binding possibility" is intended to be a separate step in claims 8 and 14. Clarification of this issue via clearer claim wording is requested.

Claim 13 (line 3) recites the term "it" which is vague and indefinite. It is unclear if the "it" is referring to the program or the computer system. Clarification of this issue via clearer claim wording is requested. Claim 14 is also rejected due its dependency from claim 13.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8-9, 13-14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimiya et al. (P/N 5,706,498).

Fujimiya et al. disclose a computer system, method, program, and computer readable medium for executable screening nucleotide sequences (abstract and Figures 2-4, col. 3, second paragraph, col. 8, first 2 paragraphs; and col. 13, first paragraph), as stated in the preamble of instant claims 1, 8, 13, and 17. Fujimiya et al. disclose storing sequence data of genes including target sequence data and key sequence data which exhibit a high degree of similarity (abstract and title and Figure 2 and col. 1, third paragraph; col. 2, fourth paragraph; col. 9, last paragraph) for homology retrieval (col. 2, fourth paragraph) including key memory and target memory (Figure 2) which represent a target and a complementary sequence data storing units, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose retrieval databases and analyzing and determining the final sequence of bases by extracting a portion of the gene probe bound to a chromosome (col. 2, third paragraph) which represents generating complementary sequence data from a probe sequence that may be bound to the target sequence and storing such data, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose a dynamic operation unit for determining the degree of similarity between the target data and the key data by utilizing base

sequence data of each (abstract), grouping homologous sequences, and retrieving the homologous gene sequence (col. 1, fifth paragraph and col. 2, second paragraph) using dynamic programming for determining the optimal solution as a whole using insertions, deletions, and substitutions for the first to last combinations of data (col. 2, last paragraph, col. 3, third and fourth paragraphs, and Figures 7a and 7b) as well as displaying maximal values of each target data in the order of higher degrees of similarity (col. 23, third paragraph) which represents an evaluation processing unit for evaluating the target nucleotide sequence data and complementary sequence data in descending order of edit distance, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose preparing a gene probe on the basis of the gene having high retrieval accuracy and analyzing and determining the binding possibility of the probe on the involved gene on a chromosome (col. 2, second paragraph), as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose a database and retrieving of sequence data using a sequence similar thereto (col. 1, first paragraph) which represents a storage unit for storing the evaluation result, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose using 10 base elements in the sequence data (col. 4, second paragraph) as well as using partial sequences (col. 4, third paragraph). Fujimiya et al. disclose a system including storage of data and a similarity degree whereby the score value at the initial condition is set to zero given the condition in which the maximal length α of the sequence is inserted or lost at one time involving partial sequences as well as setting α to 1 to get a maximal score value (col. 4, last paragraph, and col. 5, and abstract) which represents a maximum edit distance storing unit, as stated in instant claims 2, 8, 13, and 17. Fujimiya et al. disclose setting a maximal value as a score of the node and applied to the origin and subsequent lattice points until finishing the basic operation and determining the

wholly optimal disposition of the three routes (col. 5, last paragraph to col. 6, second paragraph) which represents a termination-determining unit determining evaluation carried out over maximal edit distance, as stated in instant claims 3, 9, and 14. Fujimiya et al. disclose a score value of each route is added (col. 5, last paragraph; col. 10; and Figures 7 and 8) which represents reading out each nucleotide sequence data and each maximum edit distance, as stated in instant claims 8, 13, and 17. Fujimiya et al. disclose the wholly optimal disposition is determined after the basic operations have been made (col. 6, second paragraph and Figures 3-4 and 6) and an interruption signal issued to the microprocessor when the operation is terminated (col. 24, last paragraph) which represents generating a termination signal in response to the determination result, as stated in instant claims 9 and 14. Fujimiya et al. disclose using the ability to apply dynamic programming to a local region having approximately 16 bases (col. 7, fourth paragraph).

Thus, Fujimiya et al. anticipate the instant invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28,

1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

November 21, 2006

Carolyn Smith
Examiner
AU 1631